

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC and)	
ENDO PAR INNOVATION COMPANY, LLC,)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	
BAXTER HEALTHCARE CORPORATION,)	
)	
Defendant.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively “Plaintiffs”), by and through their undersigned counsel, hereby allege against Defendant Baxter Healthcare Corporation (“Baxter”) as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,993,520 (“the ‘520 patent”), 11,135,265 (“the ‘265 patent”), and 11,207,372 (“the ‘372 patent”) (collectively “the Patents-in-Suit”), arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 21 U.S.C. § 2201, *et seq.*

THE PARTIES

2. Plaintiff Par Pharmaceutical, Inc. (“Par Pharmaceutical”) is a corporation organized and existing under the laws of the state of New York, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

3. Plaintiff Par Sterile Products, LLC (“Par Sterile Products”) is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

4. Plaintiff Endo Par Innovation Company, LLC (“EPIC”) is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677.

5. Upon information and belief, Defendant Baxter Healthcare Corporation is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, at least because this action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

7. This Court has personal jurisdiction over Baxter because Baxter is incorporated in the state of Delaware.

8. This Court has personal jurisdiction over Baxter because, *inter alia*, Baxter has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, on information and belief, following approval of Baxter’s New Drug Application (“NDA”) No. 217569 (“the Baxter NDA”) by the U.S. Food and Drug Administration (“FDA”), Baxter will commercially manufacture, use, offer for

sale, sell, and/or import Vasopressin in 0.9% Sodium Chloride Injection (“Baxter’s NDA Products”) before the expiration of the Patents-in-Suit.

9. This Court also has jurisdiction over Baxter because, *inter alia*, this action arises from actions of Baxter directed toward Delaware, and because Baxter has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Baxter regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Baxter derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

10. This court also has personal jurisdiction over Baxter because Baxter has regularly and purposefully availed itself of the privileges and benefits of this forum, having brought multiple suits in this District, including *Baxter Healthcare Corporation v. Nevakar Injectables Inc.*, 1:21-cv-01184 (D. Del. August 18, 2021); *Baxter Healthcare Corporation v. Hospira, Inc. et al.*, 1:18-cv-00303 (D. Del. February 22, 2018); and *Baxter Healthcare Corporation et al. v. Minrad Inc. et al.*, 1:09-cv-00582 (D. Del. August 6, 2009).

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

The Patents-in-Suit

12. The ’520 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the United States Patent and Trademark Office (“the USPTO”) on June 12, 2018. A copy of the ’520 patent is attached as Exhibit A.

13. The '520 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors.

14. Par Pharmaceutical is the assignee of the '520 patent. EPIC is the exclusive licensee of the '520 patent.

15. The '265 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the USPTO on October 5, 2021. A copy of the '265 patent is attached as Exhibit B.

16. The '265 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors.

17. Par Pharmaceutical is the assignee of the '265 patent. EPIC is the exclusive licensee of the '265 patent.

18. The '372 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the USPTO on December 28, 2021. A copy of the '372 patent is attached as Exhibit C.

19. The '372 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors.

20. Par Pharmaceutical is the assignee of the '372 patent. EPIC is the exclusive licensee of the '372 patent.

VASOSTRICT®

21. Vasopressin, the active ingredient in VASOSTRICT®, is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

22. On September 25, 2012, JHP Pharmaceuticals, LLC (“JHP”) submitted NDA No. 204485, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”), seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy shock or septic shock). On April 17, 2014, the FDA approved NDA No. 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

23. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP. On February 26, 2014, JHP changed its name to Par Sterile Products, LLC.

24. Par Sterile Products is the holder of NDA No. 204485, including all supplements thereto, for VASOSTRICT®.

25. Par Sterile Products submitted a supplemental NDA, including for approval of 40 units/100 mL and 20 units/100 mL presentations of VASOSTRICT® (“VASOSTRICT® Premixed Products”), which the FDA approved on April 15, 2020 and April 21, 2021, respectively.

26. According to the FDA-approved prescribing information, VASOSTRICT® is indicated “to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.” Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers.

Acts Giving Rise To This Suit

27. Upon information and belief, Baxter submitted NDA No. 217569 to the FDA pursuant to 21 U.S.C. § 355(b)(2), seeking approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of Baxter’s NDA Products.

28. Upon information and belief, following FDA approval of Baxter's NDA, Baxter will make, use, sell, or offer to sell Baxter's NDA Products throughout the United States, or import such products into the United States.

29. Upon information and belief, Baxter's NDA Products will be marketed as competing products to VASOSTRICT®.

30. Upon information and belief, in connection with the filing of its NDA as described above, Baxter provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv) ("Baxter's Paragraph IV Certification"), alleging that the claims of United States Patent Nos. 9,919,026 B2 ("the '026 patent"), 9,925,233 B2 ("the '233 patent"), 9,925,234 B2 ("the '234 patent"), 9,962,422 B2 ("the '422 patent"), 9,968,649 B2 ("the '649 patent"), 9,974,827 B2 ("the '827 patent"), 9,981,006 B2 ("the '006 patent"), 10,010,575 B2 ("the '575 patent"), 9,375,478 B1 ("the '478 patent"), 9,687,526 B2 ("the '526 patent"), 9,744,209 B2 ("the '209 patent"), 9,744,239 B2 ("the '239 patent"), 9,750,785 B2 ("the '785 patent"), and 9,937,223 B2 ("the '223 patent") are invalid, unenforceable, and/or will not be infringed by the activities described in Baxter's NDA.

31. No earlier than January 30, 2023, Baxter sent written notice of its Paragraph IV Certification to Plaintiffs ("Baxter's Notice Letter"). Baxter's Notice Letter alleged that the claims of the '026, '233, '234, '422, '649, '827, '006, '575, '478, '526, '209, '239, '785 and '223 patents are invalid, unenforceable, and/or will not be infringed by Baxter's NDA Products. Baxter's Notice Letter also informed Plaintiffs that Baxter seeks approval to market Baxter's NDA Products before these patents are scheduled to expire on January 30, 2035.

32. The Patents-in-Suit are in the same patent family as the '026, '233, '234, '422, '649, '827, '006, '575, '478, '526, '209, '239, '785 and '223 patents that were the subject of Baxter's Paragraph IV Certification and are also scheduled to expire on January 30, 2035.

33. Plaintiffs sent a letter to Baxter dated March 29, 2023, informing Baxter of the Patents-in-Suit. Baxter also has knowledge of the Patents-in-Suit based upon the filing of this Complaint.

34. Baxter's submission of the Baxter NDA to the FDA, and any commercial manufacture, use, offer to sell, sale, and/or importation of Baxter's NDA Products, has infringed and will infringe the Patents-in-Suit, as detailed below.

COUNT I
(Infringement of the '520 Patent)

35. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

36. Baxter, by submission of its Paragraph IV Certification as part of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in the United States of Baxter's NDA Products, prior to the expiration of the '520 patent on January 30, 2035.

37. Baxter's NDA has been pending before the FDA since at least January 30, 2023, the date that Baxter sent the Baxter Notice Letter to Plaintiffs.

38. The submission of the Baxter NDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's NDA Products before the expiration of the '520 patent, constitutes infringement by Baxter of one or more claims of the '520 patent under 35 U.S.C. § 271(e)(2)(A).

39. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will infringe one or more claims of the '520 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, upon FDA approval of Baxter's NDA, Baxter will intentionally encourage acts of direct infringement with knowledge of the '520 patent and knowledge that its acts are encouraging infringement.

40. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will contributorily infringe one or more claims of the '520 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, Baxter has had and continues to have knowledge that Baxter's NDA Products are especially adapted for a use that infringes one or more claims of the '520 patent and that there is no substantial non-infringing use for Baxter's NDA Products.

41. Claim 1 of the '520 patent reads as follows:

1. A method of increasing blood pressure in a human in need thereof, the method comprising:
 - a) providing a unit dosage form for intravenous administration, wherein the unit dosage form comprises:
 - i) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
 - ii) from about 1 mM to about 10 mM acetate buffer;
 - iii) 0-2% vasopressin degradation products;
 - iv) sodium chloride; and
 - v) water; and
 - b) storing the unit dosage form for at least about 24 hours at from about 0.1 units/ml to about 1 unit/ml of vasopressin or a pharmaceutically-acceptable salt thereof; and
 - c) after the storing, administering the unit dosage form to the human by intravenous administration, wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; wherein:

the unit dosage form has a pH of 3.4 to 3.8; the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

42. Baxter's NDA Products satisfy each and every element of at least claim 1 of the '520 patent, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States by Baxter of Baxter's NDA Products would infringe at least claim 1 of the '520 patent.

43. Plaintiffs will be substantially and irreparably damaged and harmed if Baxter's infringement of the '520 patent is not enjoined.

44. Plaintiffs do not have an adequate remedy at law.

45. Baxter's infringement of the '520 patent would be willful, wanton, and deliberate.

46. There is a justiciable controversy between the parties as to the infringement of the '520 patent.

COUNT II
(Infringement of the '265 Patent)

47. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

48. Baxter, by submission of its Paragraph IV Certification as part of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in the United States of Baxter's NDA Products, prior to the expiration of the '265 patent on January 30, 2035.

49. Baxter's NDA has been pending before the FDA since at least January 30, 2023, the date that Baxter sent the Baxter Notice Letter to Plaintiffs.

50. The submission of the Baxter NDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's NDA Products before the expiration of the '265 patent, constitutes infringement by Baxter of one or more claims of the '265 patent under 35 U.S.C. § 271(e)(2)(A).

51. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will infringe one or more claims of the '265 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, upon FDA approval of Baxter's NDA, Baxter will intentionally encourage acts of direct infringement with knowledge of the '265 patent and knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will contributorily infringe one or more claims of the '265 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, Baxter has had and continues to have knowledge that Baxter's NDA Products are especially adapted for a use that infringes one or more claims of the '265 patent and that there is no substantial non-infringing use for Baxter's NDA Products.

53. Claim 1 of the '265 patent reads as follows:

1. A method of increasing blood pressure in a human in need thereof, the method comprising treating the human with a kit, wherein the kit comprises:
 - a) a container, wherein the container is a drip-bag; and
 - b) a unit dosage form contained in the drip-bag, wherein the unit dosage form comprises:
 - i) vasopressin or a pharmaceutically-acceptable salt thereof at a concentration of about 0.1 units/mL to about 1 unit/mL;
 - ii) from about 1 mM to about 10 mM acetate buffer;
 - iii) dextrose, sodium chloride or combination thereof; and
 - iv) water,

wherein when iii) is dextrose, the unit dosage form has a pH of from about 3.6 to about 3.9,

wherein when iii) is sodium chloride, the unit dosage form has a pH of from about 3.5 to about 3.7, and

wherein when iii) is a combination of dextrose and sodium chloride, the unit dosage form has a pH of from about 3.7 to about 3.8;

wherein the treating the human with the kit comprises:

 - a) storing the unit dosage form for at least about 24 hours at a concentration of from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

b) after the storing, administering the unit dosage form to the human by intravenous drip wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL vasopressin or the pharmaceutically-acceptable salt thereof.

54. Baxter's NDA Products satisfy each and every element of at least claim 1 of the '265 patent, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States by Baxter of Baxter's NDA Products would infringe at least claim 1 of the '265 patent.

55. Plaintiffs will be substantially and irreparably damaged and harmed if Baxter's infringement of the '265 patent is not enjoined.

56. Plaintiffs do not have an adequate remedy at law.

57. Baxter's infringement of the '265 patent would be willful, wanton, and deliberate.

58. There is a justiciable controversy between the parties as to the infringement of the '265 patent.

COUNT III
(Infringement of the '372 Patent)

59. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

60. Baxter, by submission of its Paragraph IV Certification as part of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in the United States of Baxter's NDA Products, prior to the expiration of the '372 patent on January 30, 2035.

61. Baxter's NDA has been pending before the FDA since at least January 30, 2023, the date that Baxter sent the Baxter Notice Letter to Plaintiffs.

62. The submission of the Baxter NDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's NDA Products before the expiration of the '372 patent, constitutes infringement by Baxter of one or more claims of the '372 patent under 35 U.S.C. § 271(e)(2)(A).

63. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will infringe one or more claims of the '372 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, upon FDA approval of Baxter's NDA, Baxter will intentionally encourage acts of direct infringement with knowledge of the '372 patent and knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of Baxter's NDA, Baxter will contributorily infringe one or more claims of the '372 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Baxter's NDA Products in the United States. On information and belief, Baxter has had and continues to have knowledge that Baxter's NDA Products are especially adapted for a use that infringes one or more claims of the '372 patent and that there is no substantial non-infringing use for Baxter's NDA Products.

65. Claim 1 of the '372 patent reads as follows:

1. A method of increasing blood pressure in a human in need thereof, the method comprising providing a unit dosage form, wherein the unit dosage form consists essentially of:

- a) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
- b) a pH-adjusting agent;
- c) an acetate buffer;
- d) about 0.9% NaCl; and
- e) water;

wherein the unit dosage form has a pH of from about 3.5 to about 3.7, storing the unit dosage form for at least about 24 hours at from about 0.1 units/mL to about 1 unit/mL vasopressin or the pharmaceutically-acceptable salt thereof;

after the storing, intravenously administering the unit dosage form to the human; wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof.

66. Baxter's NDA Products satisfy each and every element of at least claim 1 of the '372 patent, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States by Baxter of Baxter's NDA Products would infringe at least claim 1 of the '372 patent.

67. Plaintiffs will be substantially and irreparably damaged and harmed if Baxter's infringement of the '372 patent is not enjoined.

68. Plaintiffs do not have an adequate remedy at law.

69. Baxter's infringement of the '372 patent would be willful, wanton, and deliberate.

70. There is a justiciable controversy between the parties as to the infringement of the '372 patent.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Baxter has infringed the '520 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA NDA No. 217569, and a declaration that Baxter will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '520 patent under 35 U.S.C. §§ 271(b) and/or (c) if Baxter commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its NDA Products before the expiration of the '520 patent;

B. A judgment that Baxter has infringed the '265 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA NDA No. 217569, and a

declaration that Baxter will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '265 patent under 35 U.S.C. §§ 271(b) and/or (c) if Baxter commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its NDA Products before the expiration of the '265 patent;

C. A judgment that Baxter has infringed the '372 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA NDA No. 217569, and a declaration that Baxter will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '372 patent under 35 U.S.C. §§ 271(b) and/or (c) if Baxter commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its NDA Products before the expiration of the '372 patent;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval by the FDA of Baxter's NDA No. 217569 be a date that is not earlier than the last expiration date of the Patents-in-Suit, including any extensions;

E. Preliminary and permanent injunctions enjoining Baxter, its respective officers, agents, servants, employees, and those persons in active concert or participation with any of them, from the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's NDA Products before the last expiration date of the Patents-in-Suit;

F. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Baxter, its respective officers, agents, servants, employees, and those persons in active concert or participation with any of them, from the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Baxter's NDA Products before the last expiration date of the Patents-in-Suit;

G. An order that damages or other monetary relief be awarded to Plaintiffs if Baxter engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of its NDA Products before the expiration of the Patents-in-Suit for the full terms thereof (including any extensions), and that such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

H. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

- I. Costs and expenses incurred by Plaintiffs in this actions; and
- J. Such other relief as the Court may deem just and proper.

Dated: March 29, 2023

Respectfully submitted,

Of Counsel:

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